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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,445	08/04/2006	**Linda Gilmer**	00952-04	8701

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UNIVERSITY OF VIRGINIA PATENT FOUNDATION
250 WEST MAIN STREET, SUITE 300
CHARLOTTESVILLE, VA 22902

EXAMINER	
FOSTER, CHRISTINE E	
ART UNIT	**PAPER NUMBER**
1641	
MAIL DATE	**DELIVERY MODE**
01/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,445	GILMER ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, drawn to a method of detecting sperm in a test sample.

Group II, claim(s) 12-15, drawn to a composition for detecting sperm in a test sample.

Group III, claim(s) 16-28, drawn to a method of purifying sperm DNA in a test sample.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The technical feature of Group I is that of a method of detecting sperm in a test sample by contacting the sample with at least one antibody directed against a sperm-specific antigen, wherein the antibody is labeled with a reporter molecule that is detected in the assay to indicate the presence of sperm in the sample.

Herr et al. (U.S. 5,436,157, see Applicant's Information Disclosure Statement filed 3/8/2007) teach methods for detecting sperm using antibodies directed against sperm-specific antigens such as the sperm head protein SP-10 (the abstract; column 2, lines 64-67; column 3,

lines 1-24; column 4, lines 17-33 and 48-67; column 5; column 6, lines 20-25; column 13, lines 30-53; column 14; column 17, line 53 to column 18, line 4; and column 19, lines 17-19). The antibodies may be labeled with by conjugation with an enzyme or dye, or may be radiolabled, depending upon what immunological method is employed (column 18, lines 4-6). Detection may be colorimetric, fluorimetric, or chemiluminescent. Post-coital samples are specifically taught at column 8, lines 8-20).

Therefore, the inventions listed as Groups I-III do not relate to a single general inventive concept because they lack the same or corresponding special technical feature.

Election of Species

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Antibody:

a. 3C6 (see claims 10 and 16)

b. 3A4 (see claims 10 and 16)

c. 3A5 (see claims 10 and 16)

d. A9 (see claims 10 and 16)

e. MHS-10 (see claims 10 and 16)

f. 8G8G8G8 (see claims 10 and 16)

Note: It is acknowledged that the claims may encompass multiple antibodies used in the same method or in the same composition, as independent claims 1, 12, and 16 recite "at least one antibody". Therefore, Applicant may elect either a single sperm-specific antibody as listed above; or alternatively two or more specified sperm-specific antibodies. Should Applicant elect more than one antibody, that group or combination of antibodies will constitute the elected species.

Sperm-specific antigen:

a. SEQ ID NO:1 (see claims 9, 14, and 26)

b. SEQ ID NO:2 (see claims 9, 14, and 26)

c. SEQ ID NO:3 (see claims 9, 14, and 26)

d. SEQ ID NO:4 (see claims 9, 14, and 26)

e. SEQ ID NO:5 (see claims 9, 14, and 26)

f. SEQ ID NO:6 (see claims 9, 14, and 26)

g. CBP86 (see claims 9, 14, and 26)

h. SAMP-14 (see claims 9, 14, and 26)

i. HUP1N (see claims 9, 14, and 26)

j. HUP2B (see claims 9, 14, and 26)

Note: It is acknowledged that Groups I-II invoke at least two antibodies directed against *different sperm-specific antigens* (see claims 8 and 13). In the event that Group I or II is elected, therefore Applicant may choose to elect either a single sperm-specific antigen as listed above; or alternatively two or more specified sperm-specific antigens. Should Applicant elect more than one antigen, the group or combination of antigens will constitute the elected species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species as listed above. The following claim(s) are generic: For Group I, claims 1, 6, and 11 are generic. For Group II: claim 12 is generic. For Group III: claims 16-24 and 27-28 are generic.

2. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. According to the guidelines in Section (f)(i)(B)(l) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group have a common structure. Although the sperm-specific antibodies listed above share a common immunoglobulin structure and are all directed against sperm-specific antigens,

the antibodiesare not regarded as being of a similar nature because the shared common structure is not a contribution over the prior art.

In particular, Herr et al. teaches the monoclonal antibody MHS-10 which is specific for the sperm antigen SP-10 (column 49, lines 49-50). Consequently, the technical feature of an antibody directed against a sperm-specific antigen is shown by Herr et al. to lack novelty or inventive step and does not make a contribution over the prior art. Similarly, although the species of antigens listed above all share the feature of being sperm-specific, this technical feature does not represent a contribution over the prior art in view of the teachings of Herr et al. of the sperm-specific antigen SP-10.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Possible Rejoinder

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571)272-8786. The examiner can normally be reached on M-F 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher L. Chin/
Primary Examiner, Art Unit 1641

/Christine Foster/
Examiner, Art Unit 1641